REMARKS

Amendments to Specification:

In paragraph 2 of the Office Action, the Examiner noted that the Specification contained trademarks and requested that they be capitalized and accompanied by a generic terminology.

Applicants have amended pages 9 and 10 of the Specification to comply with this request.

In paragraph 3 of the Office Action, the Examiner noted that the ATCC deposit number was missing on page 6 of the Specification.

Applicants have amended page 6 of the Specification to comply with this request. Applicants are also enclosing the ATCC deposit receipt and a Statement of Availability with this Response.

Applicants are also amending several other pages of the Specification to correct what appears to be typographical errors in this copy of the Specification. These errors where not present in the copy of the Specification filed with the parent application. The corrections are obvious on their face. Applicants apologize for these errors and submit that no new matter is being entered.

Amendments to Claims:

Applicants are amending Claim 21 by adding the step of contacting the F. necrophorum culture with formaldehyde to inactivate the culture. Support for this amendment can be found on page 12, first paragraph of the Specification. No new matter is being added. This amendment will be discussed in further details below.

35 U.S.C. § 102(a) Rejection

The Examiner rejected Claims 21-22 under 35 U.S.C. § 102(a) as anticipated by Liem et al, 32nd Annual Convention Proceedings, American Association of Bovine Practitioners, September 23-26, 1999, Nashville, TN.

The earliest priority date of this patent application is September 29, 1999. Applicants note that this article published less than one year before the earliest priority date of this application. The article cited by the Examiner published information about this invention and describes the work of the Applicants. Two authors on this article, D.V. Cain and S. MacGregor, are not inventors but worked under the Applicants' control and direction. As such, attached is a Declaration Under 37 C.F.R. § 1.132 by one Applicant, Douglas L. Stine, declaring that the

article describes the work of the Applicants and that D.V. Cain and S. MacGregor are not inventors but worked under the Applicants' control and direction.

Applicants believe that this Declaration should remove the cited article as a 102(a) reference. Applicants request that the Examiner withdraw this rejection.

35 U.S.C. § 102(b)/103(a)

The Examiner rejected Claims 21-22 under 35 U.S.C. § 102(b) as anticipated by Berg (EP 0406480B1). The Examiner believes that Berg discloses every element of the unamended Claim 21 and stated that Berg teaches a method of preventing footrot and liver abscesses in bovine by vaccinating bovine with a vaccine containing Fusobacterium necrophorum, that the isolates are cultured between 10 and 24 hours, that the bovine may be administered the vaccine subcutaneously, that Berg teaches a dose of about 1 ml to about 6 ml for cattle or sheep, that Berg teaches multiple injections are possible; and that the bacterial count population equal to at least 1 x 10^5 CFU/ml is inherent.

The Applicants believe that the Examiner is mistaken concerning what Berg discloses for the dosage of the vaccine. On page 3, lines 47-48, Berg states "... a dose of from about 1 to about 4 ml is generally suitable for adult sheep, and a dose of from about 2 to about 6 ml is generally suitable for adult cattle." It is well-known in the art that sheep, having a smaller body weight than cattle, take smaller doses of a vaccine. So, it is incorrect to state that Berg teaches all of the limitations of unamended Claim 21 because Claim 21 clearly indicates that the dose for cattle can range from about 1 to about 2 ml, which is below what Berg discloses for cattle.

Even though Berg discloses a lower limit of about 2 ml dosage for cattle, Berg does not provide any data to support that lower limit. In Example 1, Berg injects intramuscularly 5 ml dose into cattle, not a 2 ml dose. So, Berg fails to enable a 2 ml dose.

Applicants amended Claim 21 to include the limitation of an inactivating step where formaldehyde is used to inactivate the bacteria. This limitation is not present in Berg. Berg uses β-propiolactone to inactivate the bacteria. So, this new limitation and the fact that Berg does not enable one to use a dosage ranging from about 1 ml to about 2 ml overcomes the Examiner's § 102(a) rejection of Claim 21. Because Claim 22 depends on Claim 21, Claim 22 also overcomes the Examiner's rejection. Applicants request that the Examiner kindly withdraw this rejection.

The Examiner rejected Claims 21-22 under 35 U.S.C. § 103(a) as obvious by Berg (EP 0406480B1). The Examiner stated that Berg does not specifically disclose an isolate taken from

a bovine; rather Berg discloses an isolate obtained from sheep. The Examiner states that the invention is not limited to bacterins derived from a specific isolate because these isolates exhibit characteristics which are typical of all biovar (biotype A of *F. necrophorum* (page 3)). Further, the Examiner believes it would be *prima facie* obvious to one of ordinary skill in the art at the time of the invention was made to add isolates taken from bovine to the vaccine composition in the claimed method because Berg teaches that isolates of the invention exhibit characteristics which are typical to all biovar.

Applicants disagree with the Examiner's argument for obviousness because Berg does not teach the use of about 1 ml to about 2 ml dose of the vaccine subcutaneously in cattle, as discussed above. Berg discloses that one can use 1-4 ml dosage for sheep and 2-6 for cattle, but cattle are larger than sheep and take a lower volume of vaccine, normally. However, in this particular case, Applicants are able to administer a dose volume of about 1 to about 2 ml subcutaneously which is not described in Berg nor is it obvious to one of ordinary skill in the art at the time the invention was made from Berg.

Furthermore, amended Claim 21 now has the limitation of an inactivating step using formaldehyde. Berg does not mention formaldehyde as an inactivating agent nor does Berg provide any reason to think that formaldehyde could be substituted for β-propiolactone. As such, the amended Claim 21 overcomes the Examiner's obviousness argument, as does Claim 22 which is dependent on Claim 21. Applicants request that the Examiner withdraw this rejection.

Any questions or issues can be directed to the below signed attorney at this address. Thank you for your assistance with this matter.

Respectfully submitted,

David L. Marks
Attorney for Applicants
Reg. No. 37,881

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-7922

Date: August 5, 2005